31 March 2020

ASX Announcement

Business update and COVID-19 response

Highlights:

- **Preparation continues for the healthy volunteer component of AD-214 Phase I study due to start in mid-2020**
- **GE Healthcare (GEHC) collaboration progresses to next stage; COVID-19 mitigation actions in place**
- **Development of radio-labelled AD-214 for PET imaging delayed due to COVID-19 but impact mitigated**
- **AdAlta funded to achieve forecast AD-214 milestones under a range of operating scenarios**
- **Coronavirus-pulmonary fibrosis link reinforces importance of developing AD-214**

MELBOURNE Australia, 31 March 2020: AdAlta Limited (ASX: 1AD), the biotechnology company whose i-body platform enables the development of next-generation therapeutics to treat challenging diseases such as Idiopathic Pulmonary Fibrosis (IPF), provides an operational update in response to the current COVID-19 operating environment.

With prudent cash management actions in place and the deferral of the initiation of the strategic growth initiatives which were announced on 3 March, AdAlta is confident that existing cash resources are sufficient to achieve its forecast AD-214 milestones, including under scenarios where key programs are delayed by the external operating environment by at least three months.

The Company has also received several questions relating to opportunities and risks arising from the COVID-19 pandemic and provides a response to these in this update.

Commencement of AD-214 Phase I healthy volunteer clinical study in mid-2020 remains feasible

AdAlta is aware of reports of substantial delays or cancellation of clinical trials around the world. New guidelines for adapting clinical trials to the current operating environment are being implemented which are designed to preserve clinical resources and protect patients and clinicians. The environment remains highly fluid.

The first part of the Company's Phase I clinical program for AD-214 will be conducted in healthy volunteers in a dedicated clinical trial unit. AdAlta's clinical trial partners report that operating impacts from COVID-19 may be less severe in Phase I units and healthy

volunteer studies, and that commencement of the Company's Phase I program in mid-2020 remains feasible. AdAlta and our partners (with teams working remotely) are continuing to prepare the Phase I program for commencement of the healthy volunteer part in accordance with the Company's previously announced mid-2020 timeline.

AdAlta's risk and scenario analysis (see contingent operating plans section below) includes a delay in commencement of the Phase I clinical trial of at least three-months, which would approximately align with various projections for the time course of severe COVID-19 disruption.

GEHC collaboration progresses to Stage 3, adapted for operating environment

AdAlta and GEHC have confirmed that their collaboration to discover i-body candidates as diagnostic imaging agents will proceed to Stage 3. AdAlta has to date received an initial milestone payment and research fees for Stage 1 and Stage 2 of the collaboration which are substantially complete. The research fee for Stage 3 will be paid in instalments. The phasing of these instalments will be adjusted in the event that reduced laboratory operations or laboratory closure in response to COVID-19 impact the duration of Stage 3.

Development of radio-labelled AD-214 for PET imaging delayed

In December 2019, AdAlta announced the award of a A$1 million Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Grant to develop a radio-labelled version of AD-214 for PET imaging in clinical trials.

Preliminary results have shown that chelation agents that will bind the radioisotope can be added to AD-214. The laboratory of AdAlta's chelation chemistry collaborator has now been closed and the laboratory of the collaborator producing the radioisotope is substantially reducing operations, both in response to COVID-19.

While these closures will delay the development of the PET tracer, and potentially its introduction to the patient part of the Phase I program, by at least three months, the four-to-five-month initial healthy volunteer component of the trial does not rely upon the PET tracer being available.

All the costs associated with the PET tracer development are external to AdAlta and so this delay represents a deferral of expenditure and does not negatively impact cash reserves. The Company has been advised that the BTB Grant Funding Agreement is able to accommodate at least six months of delays and the total value of grant funds will not be affected.

Contingent operating plans

CEO and Managing Director, Dr Tim Oldham commented "AdAlta has built a strong internal plan which it can adjust in order to support business continuity. We are in the fortunate position of having a solid cash balance and the bulk of our expenditure linked to external projects so that costs move with delay. Our underlying cash burn is relatively modest."

The Company forecasts that it can manage existing funds to achieve previously announced AD-214 milestones (Phase I top line safety data in healthy volunteers; completion of pre-clinical development of radio-labelled AD-214 for PET imaging) even in the event of these being subject to delays of three months or more. Scenarios have been

developed under which AdAlta can adjust the mix, scope and pace of projects to achieve these goals and respond to more severe disruptions.

To protect our staff and the community, non-laboratory staff are working from home and laboratory staff have implemented social distancing and enhanced hygiene measures while the laboratories remain open. Should laboratories close, scientific staff will be redeployed to detailed planning of strategic growth initiatives, new target selection and partnering support.

In addition to the receipt of a second advance under the Radium R&D Tax Incentive advance facility and the reduction of board costs announced on 27 March 2020, the Company has paused all experimental work on strategic growth projects including new pipeline target selection, i-body2.0, AD-214 continuous product improvement and new indication proof of concept studies and evaluated corporate, consulting and remaining laboratory costs carefully to focus on AD-214 clinical and PET tracer and GEHC milestones.

Link between coronavirus and Idiopathic Pulmonary Fibrosis (IPF)

AdAlta's lead product candidate, AD-214 is being developed as a treatment for IPF, a degenerative and fatal disease with numerous risk factors and limited therapeutic options.

The Company is aware that several publications have reported that a substantial proportion of patients surviving SARS subsequently developed IPF[1] and that early reports suggest that COVID-19 similarly induces fibrotic lung disease.[2] This is consistent with the SARS-CoV2 virus infecting lower lung tissue, creating the repeated insult and inflammation that is believed to trigger IPF. COVID-19 infection may be a risk factor for developing IPF.

Dr Oldham commented "These publications emphasise the importance of AdAlta's efforts to develop improved therapies for IPF, and to explore the potential of AD-214 in for the benefit of all patients with fibrotic lung damage including those who may develop fibrosis as a result of coronavirus outbreaks."

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
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[1] See for example G M-K Tse, *et al*, "Pulmonary pathological features inn coronavirus associated severe acute respiratory syndrome (SARS)", J Clin Pathol 2004, 57, 260-265. Doi: 10.1136/jcp.2003.013276

[2] See for example M Hosseiny, et al, "Radiology Perspective of Coronavirus Disease 2019 (COVID-19): Lessons from Severe Acute Respiratory Syndrome and Middle East Respiratory Syndrome", American journal of Roetgenology, 2020 1-5. 10.2214/AJR.20.22969 and American College of Cardiology News Story, "Cardiologist's insights from treating COVID-19 patients in China", 12 March 2020

Notes to Editors
About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of single domain antibody protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases.

AdAlta is currently preparing for its Phase 1 clinical studies for its lead i-body candidate, AD-214. The clinical program is targeted to commence in mid-2020 following finalisation of clinical trial design. AD-214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need. The Company is also in collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta's strategy is to maximise the products developed using its next generation i-body platform by internally discovering and developing selected i-body enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

Further information can be found at: www.adalta.com.au

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